Allograft for Fusion

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Gold Standard

Comparator or Reference = Allograft
Standard of Care = Allograft
Evidence = Allograft
Practicality = Allograft
Reference

FDA choses allograft

Just in Cervical Disc Literature

Evidence

Level 1 Data supporting the use of allograft

Numerous prospective studies demonstrating efficacy and Safety

600 patients

Cervical fusion rates

90-97 percent
Over 1000 patients studies in both prospective and retrospective analysis

Mostly as graft extender.

Substantiates utility as and extender when used with autograft.

No reported safety concerns.
Enhanced Cellular Allografts

- Osteocell
- Trinity
- Vivogen
- Bio-4
- Cellentra

Practicality

- Osteoconductive at minimum
- Most cost efficient
- Evidence proves use as stand alone and graft extender
- Mildly osteoinductive
- Best Safety Profile

Future Allogenic Cells
Allogeneic Mesenchymal Precursor Cells
Off the shelf solution

- Homogeneous cell population, STRD-1 positive
- Well-controlled, efficient large-scale cell expansion
- Batch-to-batch consistency
- Stringent release criteria
- Regulated as a biological product and supported with clinical studies conducted under FDA's IND regulations

Bone marrow from universal donor
BM + stem cell-binding antibody
Magnets

Magnet

Fresh, quiescent

Master cell bank

Final, batched product for thousands of unrelated recipients

Bioreactor Cell Processing

Commercial Viability
Study Comparing Mesenchymal Precursor Cells and Autogenous Iliac

Prospective, multi-center, randomized, open-label, controlled study

Patients undergoing 1 or 2 level TLIF or PLIF procedures using PEEK interbody spacers and posterior stabilizing hardware

Study groups - 8 patients/group
  - MPC-H treated Animal (10 cc injected)
    - 25 million MPCs combined with 10 cc carrier material
  - AG treated Animal
    - 75 million MPCs combined with 10 cc carrier material

Follow-up: 1, 3, 6, 9, 12, 24 & 36 months

Evaluations

Safety
  - Adverse Events
  - Infections
  - Immunological Testing
  - Musculoskeletal
  - Laboratory tests

Efficacy
  - Fusion Assessment by CT and X-ray Images
  - Oswestry Disability Index
  - Lower Back and Leg Pain measured by VAS scores at 0-10
  - Work Productivity & Activity Index (WPAI)
  - SF-36
Radiographic Results Over Time
Patient 01-012 Treated with 25M MPCs

CT Results Over Time
Patient 01-012 Treated with 25M MPCs

Gold Standard

• Not only Gold Standard Now

• But also Gold Standard for the future.
THANK YOU!!!